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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/796,495	03/09/2004	Jon S. Wilson	3600/290	3046

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EXAMINER	
VU, QUYNH-NHU HOANG	

ART UNIT	PAPER NUMBER
3763	

MAIL DATE	DELIVERY MODE
06/22/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/796,495	WILSON ET AL.	
	Examiner	Art Unit	
	QUYNH-NHU H. VU	3763	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 May 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *32-54* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *32-54* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Amendment

Amendment and Request for Continued Examination (RCE) filed on 05/27/09 have been entered.

Claims 32-54 are present for examination.

Claims 1-31 are cancelled.

Drawings

The drawings are objected to under 37 CFR 1.83(a) because they fail to show "element 200" as described in the specification. Any structural detail that is essential for a proper understanding of the disclosed invention should be shown in the drawing. MPEP § 608.02(d). Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Beside that, element 210 shows in Fig. 7 but does not described anywhere in the Specification.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 32-39, 41-54 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schon (US 6,682,519) or Markel et al. (US 5,624,413) in view of Pourchez (US 6,001,079).

As noted that, Applicant defines the term "proximal" referred to those portions of a catheter inserted into an area of a patient's body such as a blood vessel; and the term "distal" for connection to a fluid exchange device, such as a dialysis machine or the like (Specification on page 11, lines 7-15). Meanwhile, Schon or Markel discloses opposite way. For example: In Schon, the proximal portion 34, 36 referred as portions of a catheter inserted into the blood vessel, and the distal portions 59, 61 of catheters referred as portions of catheter that outwardly from the patient's body. In Markel, the proximal portion 30, 34, 36 referred as portions of a catheter inserted into the blood vessel, and the distal portions 52, 56 of catheters referred as portions of catheter that outwardly from the patient's body.

Regarding claims 32, 41-42, 45, Schon discloses a method of surgically implanting a multi-lumen catheter into a patient, the multi-lumen catheter comprising: a multi-lumen tube portion, a proximal end 38, 40 comprising a single-lumen portion venous portion 34 and single lumen arterial portion 36. As noted that, the elements 34, 36 can be swapped names such as venous portion 36 and the arterial portion 34. A distal end 59 includes a single lumen distal venous tube portion; and a single lumen distal arterial tube 61 having a distal end.

The method comprising: making an incision in the skin of the patient at portion 72, inserting the catheter sheath 69 through the incision 72 (Figs. 1-3 or col. 4, lines 45+). The shape and size of sheath may vary to accommodate the shape of a catheter to catheters (can be catheters 16, 18) placed together (col. 10, lines 4-7); forming a subcutaneous tunnel 50, 54 having a first end 70 proximate to the incision 72 and a second end 60, 64 distance from the first end of the tunnel (col. 2, lines 42+);

According to Figs. 6A-B of Specification, they show that: a first end of subcutaneous 104 is same portion of incision 100; and a second end of subcutaneous is as location 106. Similarly, Schon shows

that a first end of subcutaneous is same portion of incision 70 or 72; and a second end of subcutaneous is location of element s 60, 64.

It is inherently that the step of forming a subcutaneous tunnel before the step of pulling the distal end 48, 52 of catheter 16, 18 through the subcutaneous tunnel 50, 54 (col. 2, line 50+; col. 10, line 63-col. 11, line 29) such that at least the distal end of the distal venous and distal arterial tube portion extend outwardly from the second end 60, 64 of the tunnels 50, 54, see Figs. 4-5.

Schon does not disclose the catheter comprising a one-piece multi-lumen having a plurality of integrally formed lumens as in claim 21, 41.

Regarding claims 32, 41-42, 45, alternatively, Markel a method of surgically implanting a multi-lumen catheter into a patient, the multi-lumen catheter comprising: a multi-lumen tube catheter assembly 10 including a first single lumen catheter 22 having a lumen 26; and a second single lumen catheter 24 having a lumen 28;

a proximal end portion 54, 58 including a single lumen 26, 28 proximal venous and arterial portion, and a distal end portion 32, 34 including a single lumen distal venous and arterial tube portion and each having a distal end 52, 56. As noted that, the venous or arterial name can be swapped name with each other.

The method comprising: making an incision in the skin of the patient at portion 70, inserting the proximal end of catheter sheath through the incision 70 into the patient (Figs. 1-2); forming a subcutaneous tunnel 48, 50 having a first end 75 proximate to the incision 70 and a second end (closed to element 76, 78, see Fig. 3) distance from the first end of the tunnel; after the subcutaneous tunnel is formed, guiding the distal end of the catheter and at least a portion of the catheter2 through the subcutaneous tunnel such that at least the distal end of the catheters extend outwardly from the second end of the tunnel (Fig. 3).

Market does not disclose the catheter comprising a one-piece multi-lumen having a plurality of integrally formed lumens as in claim 21, 41.

Pourchez discloses a catheter comprising: a one-piece multi-lumen 1 having: a plurality of integrally forming lumens 2 and 3. The catheter structure of Pourchez is used in hemodialysis treatments.

It would have been obvious at the time the invention was made to a person having ordinary skill in the art to modify the device of Schon/Market with a catheter having one-piece multi-lumen, as taught by Pourchez, in order to easy insertion into a vein of a patient during hemodialysis treatment.

Regarding claims 33-34, 48-49, this catheter device of Schon or Markel is used for hemodialysis, therefore, the distal arterial and venous tube portion of catheter must connected to the fluid exchange/hemodialysis device. Also, it is well-known in the hemodialysis art to provide the fluid exchange /hemodialysis device comprises connecting with the distal arterial portion of the catheter to the arterial leg utilizing a first connector hub, and connecting the proximal venous portion of the catheter to the venous leg utilizing a second connector hub.

Regarding claims 35-36, 38, 50, 52, the method of Schon or Markel including placing the proximal venous and arterial portion of the catheter into the circulatory system of the patient; a stabilizing cuff 14 (in Schon) or 85 (in Markel, col. 10, lines 1-6) affixed to an outer surface of the catheter; the stabilizing cuff located between the outer surface of the catheter and an interior wall of the subcutaneous tunnel.

Regarding claim 37, 39, 44, 51, 53, Schon further discloses that the subcutaneous tunnels are preferably formed using a tunneling device (not shown) such as a stainless steel trocar (dilator) which, for example, attaches to the first proximal end 59 (equivalent as a distal end of claimed invention) of the first proximal portion 48 (same as the first distal portion of claimed invention) of the first catheter 16 and pulls the proximal portion 48 beneath the skin while forming a subcutaneous tunnel 56. The end 59 of the proximal portion 48 is drawn by the device percutaneously out through an opening 60, and so on… (col. 11, lines 2-33, or col. 2, lines 42-48). A trocar/dilator is passed into the incision and out through the skin at the point of catheter insertion creating a subcutaneous tunnel. The catheter is attached to the tunneling device and pulled back through the skin tunnel, col. 2, lines 42-48.

Regarding claims 37, 39, Markel further disclose the subcutaneous tunnels in the subcutaneous 16 of the body is a manner known to those of ordinary skill in the art, col. 9, lines 60-66. It is well-known in the art to performing the step of dilating at least a portion of the subcutaneous tunnel before guiding the distal end of the catheter and at least a portion of the catheter tube through subcutaneous tunnel; wherein

the dilating step comprising sliding a sheath dilator along a shaft of a trocar longitudinally positioned in the tunnel. For example: Schon discloses this method in col. 2, lines 42-49.

Regarding claims 40, 47, 54, Schon or Markel discloses that the introducer sheath is positioned by placing a dilator/trocar device inside of the introducer sheath and passing both the dilator and the introducer sheath together into the vessel, see col. 1, lines 54-59 in Schon or col. 1, lines 51-60 of Markel). It is well-known in the art that the introducer sheath having a smooth outer contour.

Claims 43 and 46 are rejected under rejected under 35 U.S.C. 103(a) as being unpatentable over Schon or Markel in view of Pourchez and further in view of Smith, III (US 4,832,687)

Schon or Markel in view of Pourchez discloses the invention substantially as claimed. Schon/Markel in view of Martin suggests that the trocar attached catheter to perform the subcutaneous tunnel procedure, but do not clearly show a dilator includes a connector element.

Smith discloses a subcutaneous tunneling device comprising: a dilator 12 having a connector element 22 connected with the catheter 26 (Fig. 3).

It would have been obvious at the time the invention was made to a person having ordinary skill in the art to modify the device of Schon/Markel in view of Pourchez with a connector, as taught by Smith, for safety leading a catheter through a subcutaneous tunnel.

Response to Arguments

Applicant's arguments with respect to claims 32-54 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Quynh-Nhu H. Vu whose telephone number is 571-272-3228. The examiner can normally be reached on 6:00 am to 3:00 pm.

The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Nicholas D Lucchesi/
Supervisory Patent Examiner, Art Unit 3763

Quynh-Nhu H. Vu
Examiner
Art Unit 3763